COLORADO STATE BOARD OF PHARMACY September 18, 2008

Minutes

The Colorado State Board of Pharmacy meeting was convened by President E. Katherine Edelblut, R.Ph., at approximately 8:36 a.m. on Thursday, September 18, 2008 at the University of Colorado Health Sciences Center, Anschutz Medical Campus, Education Building 2, South, Room L28-2306, Aurora, Colorado 80045. Notice of this meeting was given in accordance with Division of Registrations Policy Number 80-17.

Board members attending were: Mary K. Arceneaux, R.Ph., Jeannine G. Dickerhofe, R.Ph., Rich Doyle, R.Ph., E. Katherine Edelblut, R.Ph., Paul Limberis, R.Ph., and Averil Strand, R.N.

Staff members attending were Wendy Anderson, R.Ph., Program Director; Chris Gassen, R.Ph., Chief Inspector; Billie Marseilles, R.Ph., Inspector, Susan Martin, R.Ph., Inspector; Mark O'Neil, R.Ph., Inspector; and Tia Johnson, Complaint/Licensing Analyst. Also present were Jo Kaye, Assistant Attorney General, and Wade Livingston, First Assistant Attorney General, Conflicts Counsel, to advise the Board.

APPROVAL OF MINUTES

The Board approved the minutes from the August 18, 2008 meeting and the August 21, 2008 meeting, as amended.

ADDITIONS TO THE AGENDA

Initial Decision, Dennis Hughes, Pharmacist Licensure Applicant

Additional information concerning Case #2008-3744.

Jessica Trujillo, Pharmacist Licensure Application

The REC Report

Inspector's Report

APPEARANCES

None.

HEARINGS

None.

INITIAL DECISIONS

Calvin T. Tyree, RPH 16164, Office of Administrative Courts Case 2007-0011

The Board heard oral arguments from Jo Kaye, AAG, and Richard Gleason, Esq., counsel for Mr. Tyree. At the conclusion of oral arguments, the Board, upon motion, voted to go into Executive Session pursuant to CRS 24-6-402(3)(a) to discuss with its counsel matters of pending and imminent court action, attorney client communications and matters required to be kept confidential by federal or state law. Under consideration at this time

was advice of counsel on procedural issues related to the Board's consideration of the initial decision. At the conclusion of the executive session, the Board came back into public session to determine the course of action it wished to take with regard to this matter. After consideration of the oral arguments by both parties, the record as defined in the Petitioner's Designation of Record filed with the Board on July 28, 2008, the Initial Decision, and the pleadings filed on exceptions by the parties, the Board voted unanimously to adopt the Initial Decision in its entirety except as follows:

a) Finding 11 on page 4 of the initial Decision was stricken in its entirety and replaced with the following language:

"Approximately one to three months after the February 23, 2006 arraignment, Respondent informed Detective Fazio that one of Respondent's prior pharmacist employees was being investigated by the Board in connection with the 2005 internet prescription arrangement. Pursuant to his prior agreement to assist Respondent with any state of federal actions, Fazio agreed to contact the Board on behalf of Respondent with respect to this matter."

- b) Reference in Finding 8 on page 3 of the initial Decision to "February 23, 2008" was corrected to read "February 23, 2006."
- c) Reference in Finding 9 on page 3 of the Initial Decision to "February 23, 2007" was corrected to read "February 23, 2006."

The ALJ's Discussion and Conclusions of Law, under the heading "**The Charge.**" were affirmed and adopted, as they appear on pages 6 through 8 of the Initial Decision.

d) The section of the Initial Decision titled "**Aggravation and Mitigation**" which appears on pages 9 and 10 was stricken in its entirety and is replaced with the following language:

"Respondent asserts that there are several mitigating factors concerning his failure to report the 2006 drug-related felony charges to the Board, as well as the 1987 conviction on his 1999 and 2001 applications, that should be taken into consideration. First, Respondent argues that his failure to report the 2006 drug-related felony charges to the Board was unintentional because he believed the California authorities had agreed to do so for him.

This argument is unpersuasive. Rule 9 required in clear and unambiguous terms that the Board be "immediately" notified of drug-related charges in another state. As the ALJ found, compliance with Rule 9 was Respondent's responsibility and his alone. That Respondent initially believed someone else would report for him does not relieve him of his obligation to assure such a report occurred.

Petitioner asserts that the complaint the Board filed against Respondent on February 15, 2006 relating to Respondent's failure to disclose a 1987 conviction on his 1999 and 2001 applications, which complaint ultimately led to the Stipulated LOA, constitutes an aggravating factor. Respondent argues that the prior LOA should not be considered an aggravating factor because his failure to report in that case was also unintentional.

This argument is unpersuasive because it inappropriately places weight on the underlying facts of the LOA instead of the timing of Respondent's receipt of the complaint that led to it. The record establishes that on February 15, 2006, the Board initiated the complaint against Respondent for his failure to report a prior felony conviction on his 1999 and 2001 applications for licensure. On February 23, 2006, eight days later, Respondent was arraigned in California for the 2006 drug-related felony charges. On March 6, 2006, approximately two weeks after Respondent's arraignment on the criminal charges, he filed a response to the Board's February 15, 2006 complaint.

Given these facts, by March 6, 2006 at the latest, Respondent knew the Board had filed a complaint against him for his failure to report a prior conviction, and he knew that new drug-related criminal charges had been filed against him. Yet the Board did not receive explicit information concerning the fact of the 2006 criminal charges until over a year later on April 25, 2007 when it received a copy of the felony complaint through a third party.

Whether Respondent's failure to report the prior criminal conviction was intentional or not is therefore beside the point. The fact that Respondent received the complaint leading to the LOA within a week of the criminal charges, and responded to the complaint shortly after his arraignment, should reasonably have underscored to Respondent his general reporting responsibilities and the importance of assuring the report of criminal developments to the Board.

Respondent further argues that his decision to cooperate with criminal officials who charged him with the drug-related felony in California should be considered a significant mitigating factor concerning the appropriate level of discipline. He asserts that his continued maximum effectiveness in ongoing investigations is dependent on retaining his pharmacy license."

e) The section titled "**Initial Decision**" which appears on pages 10 and 11 of the Initial Decision was stricken in its entirety and is replaced with the following language:

"Pursuant to the Act, upon a finding, as is the case here, that a licensee has engaged in unprofessional conduct, the Board may impose discipline. Sections 12-22-125(1) and 12-22-125.2(1), C.R.S. Available sanctions include a letter of admonition, probation and supervision, license restriction, license with conditions, and suspension or revocation of a license. Section 12-22-125.2, C.R.S. The Act authorized the imposition of a fine only against registrants, not individual licensees. Section 12-22-125.2(5), C.R.S.

In determining an appropriate sanction in this matter, the ALJ must give consideration to the Board's responsibilities to regulate the practice of pharmacy in order to protect the public interest under §12-22-101 of the Pharmaceuticals and Pharmacists Act ("Act"). That statute

states: "It is a matter of public interest and concern that the practice of pharmacy, as defined in this part 1, merits and receives the confidence of the public..." <u>Id</u>. In doing so, appropriate weight must be given to the aggravating and mitigating factors.

Petitioner has established Respondent violated Rule 9.00.10 and therefore Rule 1.00.10 and Section 12-22-125(1)(c), C.R.S. by failing to assure the Board was immediately notified of the filing of criminal charges against him in California in February of 2006. Petitioner has also established Respondent knew of the complaint that eventually led to the Stipulated LOA before March 6, 2006, underscoring the importance of his reporting responsibilities. Petitioner contends the appropriate sanction in this matter is revocation. Respondent, in contrast, maintains that based on all the circumstances revocation is inappropriate and only minor discipline, if any at all, is warranted.

For the reasons set forth above, Respondent's arguments in mitigation of his offense lack significant persuasion. As a licensed professional, he has shown careless disregard toward his reporting obligations to the Board. Also, the Board bears the responsibility to assure that the practice of pharmacy merits and receives "the confidence of the public." It must therefore also consider the policy ramifications of the use of Respondent's license as leverage in criminal investigations rather than a symbol warranting that confidence.

After considering the proved violation and surrounding circumstances, as well as the aggravating and mitigating circumstances as discussed above, the appropriate level of discipline is probation with terms and conditions as follows."

The Board then ordered that Mr. Tyree's license to practice pharmacy in the State of Colorado be placed on probation for a period of not less than three years. Credit toward satisfying the period of probation will only be given when Mr. Tyree is in total compliance with all provisions of the Final Agency Order ("FAO").

Terms of probation include taking and passing the Professional and Problem Based ("ProBE") Ethics Course within one year from the effective date of the FAO. Mr. Tyree is to take and pass the MPJE Examination within six months of the effective date of the FAO. During the period of probation, Mr. Tyree may not serve as a consultant pharmacist, preceptor, or pharmacist manager. He must also provide copies of the FAO to all employers, pharmacist managers, and immediate supervisors. In addition, his managers and supervisors must make reports to the Board.

The Board then voted to delegate the issuance of the drafting and signing of the FAO to its Program Director.

Dennis Hughes, Pharmacist Licensure Applicant

The Board then considered the Initial Decision in the above-referenced matter. The Initial decision was rendered on August 15, 2008 by Administrative Law Judge ("ALJ") Robert N. Spencer. ALJ Spencer determined that Mr. Hughes should be granted a license which

should be subject to three years probation and such evaluation and monitoring as the board deemed appropriate. On behalf of the Board, Ms. Kaye had filed a Designation of Record and a Motion for Extension of Time to File Exceptions on September 9, 2008. Mr. Hughes had not filed a designation of any part of the record within twenty days of the notification of the Initial Decision. Mr. Hughes appeared before the Board via telephone and told the Board members that he did not intend to file exceptions in the matter and his desire was for the Board to consider the Initial Decision that day. Counsel for the Board concurred and subsequently verbally withdrew the Motion for Extension of Time to File Exceptions in order to facilitate the Board's review of the case. Wade Livingston from the Office of the Attorney General was present as Conflicts Counsel during the meeting. The Board, on its own motion, reviewed the Designated Record and the Initial Decision in its entirety. It then voted unanimously to adopt the Initial Decision and outlined the terms and conditions for probation. The Board determined the conditions for probation as follows. Mr. Hughes would be issued a license subject to a period of probation not less than three years. Credit towards satisfying the period of probation would only be given during periods of time when he is employed in the State of Colorado a minimum of eighty hours per month as a pharmacist or is engaged in employment for which a pharmacist license is required, and during periods of time in which he is in total compliance with all provisions of the Final Agency Order ("FAO"). Within thirty days of the effective date of the FAO, Mr. Hughes must undergo an evaluation by Peer Assistance Services ("PAS") to assess whether he has any conditions which may endanger the health and safety of the public. If PAS determines that he needs treatment, he must enter into a contract with the Rehabilitation Evaluation Committee ("REC") and comply with the terms and conditions of that contract. Within one year from the effective date of the FAO, he must complete and pass the Professional and Problem Based ("ProBE") Ethics Course. He must submit proof of completion of the course to the Board within ten days of successful completion. Mr. Hughes will not be allowed to be a consultant pharmacist, preceptor, or pharmacist manager during the period of probation. He must also disclose the FAO to all employers, pharmacist managers, and immediate supervisors at each location at which he intends to practice pharmacy. He must notify the Board within three days of starting or changing locations of employment. Manager/Supervisor Reports and Quarterly Status Reports are also terms of probation.

The Board then voted to delegate the issuance of the drafting and signing of the FAO to its Program Director.

REPORTS

President's Remarks

None.

Program Director's Report

Ms. Anderson discussed proposed changes to rule 6.00.30. After due consideration, the Board voted to move the proposed changes to hearing.

Ms. Anderson provided the Board with statistics for fiscal year 2008. She then discussed issues regarding pharmacy interns practicing as such prior to being licensed. After discussion, the Board directed staff to proceed with licensing these individuals, but to issue notices to those interns who have practiced prior to licensure. In addition, it directed

staff to send notices to the employing pharmacies, as well as the intern's preceptor. In addition, the Board directed staff to include an article about this issue in its next newsletter.

Ms. Anderson then advised the Board that the Department had received another Federal Grant to enhance the Electronic Prescription Drug Monitoring Program. She stated that work will begin in the next couple months. Ms. Anderson updated the Board on the Pharmacy Technician Taskforce which met on September 16, 2008.

Colorado Pharmacists Society (CPS) - Rich Doyle, RPh

Rich Doyle reported that the next continuing education (CE) program would be the 2008 Colorado Pharmacist Society (CPS) Annual Fall Meeting to be held September 24-26, 2008 at the Summit Conference Center. Programming will include two dinner CE programs and an exhibit hall. This will be the first year that the Annual Fall Meeting's Exhibit Hall will be held in conjunction with the University of Colorado School of Pharmacy's Professional Opportunities Day where pharmacy students have a chance to meet with potential future employers. Details about the program and registration are available on the CPS website, www.copharm.org.

In recognition of the National Pharmacist Month in October, CPS will be staffing phones for Pharmacists Line 9 on October 23, 2008 from 4-5:30 p.m. The public will be invited to call 9 News to speak to a pharmacist. Included with this event will be an interview with a pharmacist discussing the value of pharmacist services.

The next CE program is the 17th Annual Winter CE Seminar, January 18-21, 2009 at the Sheraton in Steamboat Springs, where 15 hours of CE will be provided. Details will be available on the CPS website www.copharm.org.

Governor's Expert Emergency Epidemic Response Committee (GEEERC) - Paul Limberis, RPh

Paul Limberis reported that the Governor's Expert Emergency Epidemic Response Committee would not meet until January 2009. He did pass out a draft copy of the Colorado Department of Public Health and Environment's "Guidance for Alterations in the Healthcare System During an Influenza Pandemic." He requested comment from the Board members on the draft at the next meeting.

Intern & School Relations - Jeannine Dickerhofe, RPh

Cathy Jarvis from the University of Colorado School of Pharmacy reported that the school's nontraditional Doctor of Pharmacy Program had been in existence for ten years. Kathleen McCartney, PharmD, Coordinator for Continuing Education and Operations at the School, detailed the program for the Board.

Legislation - Jeannine Dickerhofe, RPh.

The Immunization Task Force will be meeting September 30, 2008. The Task Force members will be presenting proposed rules changes at this meeting and will decide which changes will be forwarded to the Board of Pharmacy.

The work group established by SB 135 will make recommendations and establish standards for technology used to transmit and exchange insurance information in a standardized, printed insurance card. Val Kalnins and Jim Driscoll are serving as the pharmacy representatives on this work group. The group met on July 18, 2008 and reviewed the standards that need to be incorporated in the electronic transmission. A meeting was planned for September 19, when Texas, the only other state pursuing a similar electronic ID system, was to discuss their process and any lessons learned. Due to a scheduling conflict the meeting has been postponed and a new date will be announced. For more information about the proposed rules or amendments, you can contact Christine Gonzales-Ferrer, Compliance Assistant at 303-894-2157 at the Department of Regulatory Agencies.

The Colorado Pharmacists Society (CPS), RxPlus, Colorado Retail Council, Kaiser and the Pharmaceutical Manufacturers Association have developed an education program on what can be done to keep pharmaceuticals out of the environment. The first presentation of this program will be on September 26 at Pikes Peak Community College, where Representative Stephens will be leading the discussion of various strategy options.

The Legislative Health Care Task Force is considering 10 bill drafts. Bill 5, titled, "E-Prescribing" will be focusing on electronic prescribing. This bill will be discussed at the next Colorado Pharmacy Coalition meeting.

Rules - Rich Doyle

None

Inspectors

Mr. Gassen reported a situation involving a pharmacy, located within a hospital setting, in which repeated attempts were made by Board staff over the past six months to have this pharmacy submit an application to the Board for a "satellite" at the same location as the pharmacy. Mr. Gassen explained that the purpose of a "satellite" is to inform the Board, by application, of the pharmacy's intent to store additional prescription drug stocks in a designated area outside of the pharmacy's principle compounding/dispensing area but within the same location as the registered pharmacy. Mr. Gassen reported that Board staff continued to find prescription drug stocks stored in the hospital's materials management department during a visit to the hospital in September and no application had been submitted to the Board.

After due consideration, the Board directed its staff to initiate a complaint against the registration of the pharmacy as well as the license of the pharmacist manager.

OLD BUSINESS

Miscellaneous

Pueblo Community Health Center Pharmacy & Automated Cassette Packaging

The Board considered and noted the information requested from Pueblo Community Health Center Pharmacy. It directed staff to review and propose changes to the rules for return to stock prescriptions.

Walgreen Co. and Electronic Maintenance of Prescription Orders

The Board reviewed an Agenda Memorandum from Mr. Gassen concerning Walgreen Co.'s request for electronic maintenance of prescription orders. After thorough review and discussion of the available information, the Board denied the request.

Stipulations

Almeida, Wendell A., RPH 11053

The Board reviewed an Agenda Memorandum from Tia Johnson, Complaint/Licensing Analyst, concerning Mr. Almeida's request for changes to the requirements of his Stipulation and Final Agency Order. After due consideration of the available information, the Board approved Mr. Almeida's request.

Wal-Mart Pharmacy #10-1199, PDO 6-2

The Board considered correspondence from Wal-Mart Stores, Inc. requesting release of Wal-Mart Pharmacy #10-1199 from the terms of its Stipulation and Final Agency Order. The Board also considered a report from Ms. Johnson. After due consideration, the Board voted to deny Wal-Mart's request for release of Wal-Mart Pharmacy #10-119 from the terms of its Stipulation and Final Agency Order.

NEW BUSINESS

Complaints

Doherty, Robert J., RPH 16511 (suspended)

2009-0228

After due consideration of the available information, the Board voted to issue a Letter of Admonition for violations of the Pharmaceuticals and Pharmacists Act and Board regulations.

Goff, Trevor J., RPH 17832

2008-3993

A motion was made, seconded, and carried to dismiss the case as being without merit.

Harris, Kelli D., RPH 15791

2008-390

A motion was made, seconded, and carried to dismiss the case as being without merit.

Hartig, Thomas, RPH 10161

2008-3807

After due consideration of the available information, the Board voted to issue a Letter of Admonition for violations of the Pharmaceuticals and Pharmacists Act and Board regulations.

Pharmacorp, Inc., Unregistered

2009-0141

A motion was made, seconded, and carried to dismiss the case.

The Clinic Pharmacy, PDO 56-4

2009-0130

After due consideration of the available information, the Board voted to refer the case for discipline.

Walgreen Pharmacy # 07581, PDO 558

2009-0229

A motion was made, seconded, and carried to dismiss the case. The Board found that there was no reasonable cause to warrant further action at this time.

LICENSING

Other Outlets, New

The Board approved the registration of 1 new other outlet.

Prescription Drug Outlets, New (In-State)

The Board approved the registrations of 6 new in-state prescription drug outlets.

Prescription Drug Outlets, New (Out-of-State)

The Board approved the registrations of 8 new nonresident prescription drug outlets.

Manufacturers, New

The Board approved the registrations of 1 new manufacturer.

Wholesalers, New (In-State)

The Board approved the registrations of 1 new in-state Wholesalers.

Wholesalers, New (Out-of-State)

The Board approved the registrations of 9 new out-of-state Wholesalers.

Licensure by Examination

The Board ratified the licensure of 77 applicants for licensure by examination.

Licensure by License Transfer

The Board ratified the licensure of 13 applicants seeking licensure through license transfer. It was noted that these licensees met all of the requirements for licensing under the provisions of section 12-22-116, C.R.S.

Licensure Issues

Pharmacist Licensure Issues

Trujillo, Jessica, RPH Applicant

The Board reviewed an Agenda Memorandum from Ms. Johnson. After due consideration of the available information, the Board voted to table further review and processing of Ms. Trujillo's application, pending receipt of additional information.

Out-of-State Wholesaler Licensure Issues

Pharmacorp, Inc., WHO Applicant

The Board reviewed an Agenda Memorandum from Mr. Gassen. After due consideration of the available information, the Board voted to issue an out-of-state prescription drug wholesaler registration to Pharmacorp, Inc.

MISCELLANEOUS

Correspondence, etc.

NABP - Internet Drug Outlet Identification Program

The Board reviewed and noted this information.

Rx Beat - Summer 2008

The Board reviewed and noted this information.

EXECUTIVE SESSION

Board President E. Katherine Edelblut moved that the Board enter into executive session as authorized by CRS 24-6-402 subsection (3)(a) roman (IIII) to discuss matters which are required by law to be kept confidential. Specifically, the provisions of law requiring these matters to be kept confidential are:

CRS 24-4-402 subsection (3)(a) romans (II) and (III), and section 13-90-107(b), which protect as confidential communications with counsel that are matters of pending or imminent litigation, or are otherwise subject to the attorney-client privilege, and CRS 25-1-1201 et sequitor, which protects the confidentiality of information pertaining to individual medical records.

The motion was unanimous.

Case Status Reports

The Board read and discussed the REC report.

The Board read and discussed the case status report from Leslii Lewis, Office of Expedited Settlement.

The Board read and discussed the September 18, 2008 case status report from Ms. Kaye.

The Board discussed all items referred to it earlier in the meeting as well as matters confidential by law.

OPEN SESSION

The Board accepted applicant PR09-155 into the REC.

The Board voted to initiate a complaint against Robert Doherty, RPh #16511 (suspended) for failing to comply with the terms of his REC contract.

2008-3768

A motion was made, seconded, and carried to dismiss the case as being without merit.

2008-3797

After due consideration of the available information, the Board voted to issue a Letter of Admonition for violations of the Pharmaceuticals and Pharmacists Act and Board regulations.

2008-3904

A motion was made, seconded, and carried to dismiss the case. The Board found that there was no reasonable cause to warrant further action at this time.

2008-3939

A motion was made, seconded, and carried to dismiss the case. The Board found that there was no reasonable cause to warrant further action at this time.

2009-0122

After due consideration of the available information, the Board voted to issue a Letter of Admonition for violations of the Pharmaceuticals and Pharmacists Act and Board regulations.

ADJOURNMENT

The Board adjourned at approximately 1:47 p.m.

Approved by E. Katherine Edelblut, RPh, President Date: October 16, 2008